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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,029	01/09/2006	P. Jeffrey Conn	53450-00010	3750

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FOX ROTHSCHILD LLP
100 PARK AVENUE
SUITE 1500
NEW YORK, NY 10017

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,029	CONN ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,7,10-12 and 14-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3,6,7,10-12 and 14-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3, 6-7, 10-12 and 14-18 are presented for examination.

Claims 2, 4-5, 8-9 and 13 were cancelled via the Preliminary Amendment dated January 9, 2006.

Upon further consideration of the claimed subject matter, the restriction requirement of July 11, 2007 has been VACATED in lieu of the following requirement, which supersedes the previous requirement of July 11, 2007.

Requirement for Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 11, drawn to a pharmaceutical composition comprising an mGluR4 receptor positive allosteric modulator or a pharmaceutically acceptable salt thereof and an antiparkinsonian agent and a pharmaceutically acceptable carrier or excipient.

Group II, claim(s) 12, drawn to a pharmaceutical composition comprising an mGluR4 receptor positive allosteric modulator or a pharmaceutically acceptable salt thereof and a neuroleptic agent and a pharmaceutically acceptable carrier or excipient.

Group III, claim(s) 1, 3, 6-7, 10 and 14-18, drawn to a method for treating, preventing the progression, ameliorating, controlling or reducing the risk of a movement disorder in a patient in need thereof that comprises administering to the patient a therapeutically effective amount of an mGluR4 receptor positive allosteric modulator or a pharmaceutically acceptable salt thereof.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the compound N-phenyl-7-(hydroxyimino)cyclo-propa[b]chromen-1a-carboxamide [see instant claim 10; see also, e.g., p.763 of Annoura et al., "A Novel Class of Antagonists for Metabotropic Glutamate, 7-(Hydroxyimino)cyclopropa[b]chromen-1a-carboxylates", *Bioorg. Med. Chem. Lett.*, 6, 1996 (cited by Applicant), specifically compound 4b, which provides for an N-phenyl

group attached to the core 7-(hydroxyimino)cyclopropa[b]chromen-1a-carboxylate] was already known in the art and, thus, cannot be considered the unifying feature of the inventions of Groups I-III because it fails to demonstrate a contribution over what was already known in the prior art at the time of the invention.

Furthermore, the inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the invention listed as Group I requires the administration of an antiparkinsonian agent, which is not required for the practice of the inventions of Groups II or III, and the invention listed as Group II requires the administration of a neuroleptic agent, which is not required for the practice of the inventions of Groups I or III. Moreover, though each of inventions I-III require the administration of an mGluR4 receptor positive allosteric modulator (which fails to be a special technical feature as noted *supra*), the inventions of Groups I and II clearly require a combination therapy, which constitutes interactive effects between the two agents unique to the claimed combination that is neither required by nor present in any one or more of the other claimed inventions. For these reasons, the inventions listed as Groups I-III fail to share a common special technical feature and, thus, also fail to set forth a single general inventive concept.

Election of Species Requirement

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Election of Invention I requires Applicant to make the following species elections:

(i) Election of a **single disclosed specie** of mGluR4 receptor positive allosteric modulator from those specifically disclosed at, e.g., p.4, l.10-p.7, l.2 of the instant specification; **and**

(ii) Election of a **single disclosed specie** of antiparkinsonian agent from those specifically disclosed at, e.g., p.10, l.23-32 of the instant specification.

Election of Invention II requires Applicant to make the following species elections:

(iii) Election of a **single disclosed specie** of mGluR4 receptor positive allosteric modulator from those specifically disclosed at, e.g., p.4, l.10-p.7, l.2 of the instant specification; **and**

(iv) Election of a **single disclosed specie** of neuroleptic agent from those specifically disclosed at, e.g., p.11, l.6-20 of the instant specification.

Election of Invention III requires Applicant to make the following species elections:

(v) Election of a **single disclosed specie** of movement disorder from those specifically claimed (see, e.g., claim 3) **or** from those specifically disclosed at, e.g., p.7, l.31-p.8, l.13 of the instant specification; **and**

(vi) Election of a **single disclosed specie** of mGluR4 receptor positive allosteric modulator from those specifically claimed (see, e.g., claim 10) **or** from those specifically disclosed at, e.g., p.4, l.10-p.7, l.2 of the instant specification; **and**

(vii) Election of whether the mGluR4 receptor positive allosteric modulator:

(a) **IS NOT** administered in combination with another agent (see, e.g., claim 1) **or**

(b) **IS** administered in combination with another agent (see, e.g., claims 6-7).

Should Applicant elect (b), wherein the mGluR4 receptor positive allosteric modulator **IS** administered in combination with another agent, Applicant is further required herein to elect a **single disclosed specie** of agent to be combined with the mGluR4 modulator from those specifically claimed (see, e.g., claims 6 or 7) **or** from those specifically disclosed at, e.g., p.10, l.4-p.11, l.20 of the

instant specification.

Applicant is cautioned that the election of a particular specie of compound and/or disease, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

The following claims are generic: claims 1, 3, 6-7, 10-12 and 14-18.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Regarding the species of therapeutic combinations claimed [i.e., an mGluR4 receptor positive allosteric modulator with or without an additional agent (such as, e.g., an antiparkinsonian agent, neuroleptic agent, etc.)], the claimed combinations lack the same or corresponding special technical feature because the components of each combination are structurally and/or chemically distinct from one another such that a comprehensive search of any one of the combinations would not *necessarily* result in a search for any one of the other claimed combinations. Furthermore, the interaction between the compounds contained within each discrete combination results in a unique interaction specific to that particular combination and, thus, the interactive effects seen with one combination would not necessarily render obvious or suggest any one or more of the other combinations claimed.

Furthermore, the species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical feature for the following reasons: the compound N-phenyl-7-(hydroxyimino)cyclopropa[b]chromen-1a-carboxamide [see instant claim 10; see also, e.g., p.763 of Annoura et al., "A Novel Class of Antagonists for Metabotropic Glutamate, 7-(Hydroxyimino)cyclopropa[b]chromen-1a-carboxylates", *Bioorg. Med. Chem. Lett.*, 6, 1996 (cited by Applicant), specifically compound 4b, which provides for an N-phenyl group attached to the core 7-(hydroxyimino)cyclopropa[b]chromen-1a-

carboxylate] was already known in the art at the time of the invention.

Regarding the species of mGluR4 receptor positive allosteric modulators, additional agents, antiparkinsonian agents or neuroleptic agents, such genera of agents encompass such a breadth of compounds that are structurally and/or chemically distinct and/or dissimilar from any one single other compound from any one single other generic formula encompassed by the claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other compounds within the claimed genus. Furthermore, in consideration of the number and breadth of compounds contained within each genera, the disparate nature and breadth of compounds encompassed by each of the claimed genera precludes a quality examination on the merits, not only because a burdensome search would be required for the entire scope of the claim(s), but also because the consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112, would be unduly burdensome. In addition, though Applicant has recognized a common functionality to the claimed compounds, e.g., that they are capable of treating the claimed movement disorders, it remains that the art does not necessarily recognize such a function as being shared by the entire claimed genera of mGluR4 receptor positive allosteric modulators, additional agents, antiparkinsonian agents or neuroleptic agents and, as a result, does not necessarily recognize their equivalency or interchangeability.

Regarding the species of movement disorders, the species are independent or distinct because such diseases as recited in the present claims for which the compound(s) must be therapeutically effective are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of active agent, frequency of treatment, etc.) and patient population such that a comprehensive search for the claimed compound in an amount effective to treat, for example, Parkinson's disease, would not necessarily anticipate, suggest or render obvious the administration of the same or different compound in an amount effective to treatment an etiologically and pathophysiologically

distinct disorder, such as Huntington's disease. Notwithstanding that Applicant may have established an underlying commonality to this genus of disorders, namely that each is treatable using any one or more of the claimed compounds, it remains that the art does not necessarily recognize such a shared characteristic as being common to the entire genera of diseases encompassed by the claims, nor does the art necessarily recognize each as amenable to the same type of pharmacologic therapy. Each is considered patentably distinct from the others because the patient populations, dosage amounts and therapeutic protocol for treating the claimed disorders are each unique to the type of disorder being treated such that a comprehensive search for the claimed compound(s) in an amount effective for the treatment of a particular disorder in the prior art would not necessarily encompass a comprehensive search of the patent or non-patent literature for the claimed compound in an amount effective for the treatment of any one or more other disorders.

Applicant is advised that a reply to this requirement is REQUIRED to include an (1) identification of the invention for examination on the merits, (2) identification of the single disclosed species elected consonant with the requirements set forth *supra* and (3) a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right

to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in

scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

April 16, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614